File No. 1065.26(A)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Ricci, et al EXAMINER: O'Connor

SERIAL NO.: 09/500,038 ART UNIT: 3732

FOR: Dental Implant System with Repeating Microgeometric Surface Patterns.

FILED: 02/08/00

DECLARATION OF JOHN L. RICCI OF PRIOR INVENTION UNDER 37 C.F.R. 1.131 AND EXPERT OPINION UNDER 37 C.F.R. 1.132

Hon. Director of Patents and Trademark
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Sir:

I, John L. Ricci, do hereby declare and aver as follows:

1. I am a member of the inventive entity of the above-referenced application for patent.

2. This application is a 35 U.S.C. 120 successor-in-interest, through three mesne co-pendant applications, of App. Serial No. 08/146,790, filed November 2, 1993. I have been a named inventor upon all of these applications going back to said 1993 parent application.

Abandoned

3. More particularly, the inventive entity of said 1993 application and its successors, filed in 1995, 1996, and 1997 respectively, was that of Harold Alexander, Charles S. Naiman, and myself.

4. The 1993 parent application represented the end result of approximately four years of research and experimentation by the inventive entity. This fact is recited in, and formalized by, a final project report to the National Science Foundation dated November 6, 1992, which is attached as Exh. A herewith. While authored by the principal investigator, that is, the late Charles S. Naiman, it reflects the collective work of Dr. Alexander and myself, as well.

Proof of conception

5. This NSF final project report indicates that substantially all of the subject matter of the 1993 patent application had, at least, been conceived prior to November 6, 1992.

6. As may be noted from the dates upon said report of Exh. A, the actual research was conducted during the period of January through September of 1992, indicating that the grant proposal was submitted in 1991. However, we had engaged in research in this area as early as 1989.

7. Since the filing of the patent application in 1993, the inventive entity has actively pursued developmental efforts and has undertaken to reduce its invention to practice in a commercial, as well as a scientific, sense as is reflected in our merger of about March 2000 with BioLok International, Inc., Deerfield Beach, Florida, which has and is exploring the dental, orthopedic, intra-ocular, transcutaneous, and many other applications of this technology which relates to the use of ordered or patterned microgrooving of

surfaces in the micron range to achieve enhanced bioaffinity of biologic to inorganic surfaces.

8. Also, the co-inventors have published various papers since 1993 explaining to their peers the development of their research, and its reduction to practice in vitro and in animal studies during the 1992-99 period. As such, the inventive entity has, in my opinion, been most diligent in its effort to reduce this technology to practice, whether defined in scientific or commercial terms. The first commercial products using this technology will be marketed this year by BioLok.

9. In view of the above, no question can exist but that the conception of the subject matter of the above-referenced application occurred before the §102(e) and 371 dates, namely, April 26, 1995, of U.S. Patent No. 5,588,838 (1996) to Hansson, et al, and said NSF final report project also indicates that conception occurred even prior to the date of the original Swedish priority document of October 28, 1992, given that all of our research under the NSF grant had been completed by September, 1992. As such, the final report, although dated November 6, 1992, simply represented a summary of this earlier research.

10. With respect to U.S. Patent No. 5,989,027 (1999) to Wagner et al entitled Dental Implant having Multiplied Textured Surfaces, said application bears an effective date of October 2, 1997 and is predicated upon a PCT filing date of December 8, 1995. There is no reference to any earlier

§119 or 120 filing date, in any jurisdiction. Accordingly, all statements above set forth relative to Hansson are certainly applicable to Wagner given that its earliest effective date is well subsequent to the filing date of the 1993 parent of this application.

11. For the above reasons, the present invention is clearly earlier in time than that of either of the cited references, namely, Hansson or Wagner. However, as a matter of record, I wish to note that the dimensionality of the microgrooving of Hansson is, at its smallest, that of 0.02 millimeters, i.e., a dimension which is greater than most of the range of 2 to 25×10^{-9} meters of the present invention. In other words, the micro-roughness of Hansson, as he terms his surface effect, is measured on the order of thousandths of a meter while the surface dimension of my invention is measured on the order of millionths of a meter. As such, the smallest possible dimension employed in the micro threads of Hansson is barely equal to that of the greatest possible dimension, that is, 25 microns employed in the microgeometric repetitive pattern of the instant invention, in which 100 microns is used in Hansson's preferred embodiment.

13. The reference to Wagner uses an essentially random roughness or an irregular porous surface. Accordingly, there is no organization to the surface pattern of the implants of Wagner, nor is the dimensionality thereof within the same range of that employed in the present invention or even that of Hansson. Also, the effected molecular cell biology, regarding the rate,

orientation and directionality of growth of colonies of cells, does not exist in the teaching of Wagner, given that the dimensionality of the height of the surfaces thereof is at least an order of magnitude greater than that employed in the present invention, and the surface dimensions thereof are random.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements are made with the knowledge that willful, false statements and the like so made, are punishable by fine or imprisonment, or both, under 18 United States Code 1001, and that such willful false statements may jeopardize the validity of the application or of any patent issued thereupon.

FURTHER THIS AFFIANT/DECLARANT SAYETH NAUGHT

JOHN L. RICCI

Nov. 16, 2004
DATE

Exhibits:

A. Final Report to NSF of 11/6/92.

NSF Grant Conditions (Article [redacted]GC-1, and Article 9, FDP-II) re[redacted]ubmission of a Final Project Report (NSF Form 98A) to the NSF program officer no later than 90 days after the expiration of the award. Final Project Reports for expired awards must be received before new awards can be made (NSF Grant Policy Manual Section 677).

Below, or on a separate page attached to this form, provide a summary of the completed project and technical information. Be sure to include your name and award number on each separate page. See below for more instructions.

PART II - SUMMARY OF COMPLETED PROJECT (for public use)

The summary (about 200 words) must be self-contained and intelligible to a scientifically literate reader. Without restating the project title, it should begin with a topic sentence stating the project's major thesis. The summary should include, if pertinent to the project being described, the following items:

- The primary objectives and scope of the project
- The techniques or approaches used only to the degree necessary for comprehension
- The findings and implications stated as concisely and informatively as possible

See attached -

PART III - TECHNICAL INFORMATION (for program management use)

List references to publications resulting from this award and briefly describe primary data, samples, physical collections, inventions, software, etc. created or gathered in the course of the research and, if appropriate, how they are being made available to the research community. Provide the NSF Invention Disclosure number for any invention.

See attached -

Charles L. Ramm	11/6/92
Principal Investigator/Project Director Signature	Date

IMPORTANT:
MAILING INSTRUCTIONS
Return this *entire* packet plus all attachments in the envelope attached to the back of this form. Please copy the information from Part I, Block I to the *Attention block* on the envelope.

Part II—Summary of Completed Project

This study's rationale is that oriented micromachined surfaces alter the behavior of cells attached to them and that cells derived from different tissues respond differently to these surfaces. This Phase I project documents the specific in vitro effects of surface microgeometry on colony formation kinetics of rat tendon fibroblast (RTF) cells and rat bone marrow (RBM) cells. The objective is to create three types of implant surfaces: a surface that enhances bone growth and discourages soft tissue growth, to achieve good bony fixation; a surface that encourages soft tissue growth and mitigates against bone growth, to achieve soft tissue integration; and a surface that acts as a barrier to (particularly soft fibrous) tissue growth, to prevent soft tissue migration into bone attachment areas.

Different surface microgeometries, produced by microlithography, were found to cause directional RTF and RBM cell growth and control overall growth to different degrees, confirming our hypothesis that such surfaces favor one or the other type of cell growth and strongly direct that growth.

An improved, longer-lived hip arthroplasty device (as one example of a commercial application) would incorporate these differential surfaces to achieve optimal results by selectively encouraging or discouraging site-specific ingrowth of tissue types.

Exh A

OMB Number 345-0058

NATIONAL SCIENCE FOUNDATION
1800 G STREET, NW
WASHINGTON, DC 20550

BULK RATE
POSTAGE & FEES PAID
National Science Foundation
Permit No. G-69

PI/PD Name and Address

Charles S. Naiman
Orthogen Inc
One Irving Place
New York NY 10003

NATIONAL SCIENCE FOUNDATION
FINAL PROJECT REPORT

PART I - PROJECT IDENTIFICATION INFORMATION

1. Program Official/Org. Ritchie B. Coryell - III

2. Program Name DIV OF INDUSTRIAL INNOVATION INTERFACE

3. Award Dates (MM/YY) From: 01/92 To: 09/92

4. Institution and Address
Orthogen Inc
1 Irving Place Suite 31GI
New York NY 10003-9704

5. Award Number 9160684

6. Project Title
Joint Implant Surfaces

This Packet Contains
NSF Form 98A
And 1 Return Envelope